IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BEST MEDICAL INTERNATIONAL, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-1599-MN
	)	
VARIAN MEDICAL SYSTEMS, INC., and VARIAN MEDICAL SYSTEMS INTERNATIONAL AG,	)	
	)	
Defendants.	)	

DEFENDANTS VARIAN MEDICAL SYSTEMS, INC. AND VARIAN MEDICAL SYSTEMS INTERNATIONAL AG'S OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(c)

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I. INTRODUCTION[1]

Three of the four patents asserted by BMI against Varian in this case claim conventional implementations of abstract ideas that do not improve either computer technology or linear accelerator technology and that are ineligible for patent protection under 35 U.S.C. § 101. Accordingly, Varian brings this motion against all asserted claims (13, 15, 19) of the '175 patent, claims 44 and 46 of the '096 patent, and claim 42 of the '283 patent.[2] As explained below, these claims recite either generic optimization algorithms or purported, but general, improvements in radiation treatment planning without any limitations on ***how*** to achieve those improved results. None of these claims contains an inventive concept that would transform the claimed abstract idea into patent-eligible subject matter. Rather, the claims recite generic components and technology that are also conventionally ordered and thus insufficient as a matter of law to salvage the claims from the realm of the abstract. Thus, Varian respectfully requests that the Court grant this motion to dismiss under Section 101 and Federal Rule of Civil Procedure 12(c).

II. NATURE AND STAGE OF THE PROCEEDINGS

Varian is a pioneer in the global fight against cancer. Varian developed the first fully rotational radiotherapy linear accelerator ("linac") for cancer treatment in 1960. Varian has also

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[1] "Varian" refers to Defendants Varian Medical Systems, Inc. and Varian Medical Systems International AG; "BMI" refers to Plaintiff Best Medical International, Inc.; "the '175, '096, and '283 patents" respectively refer to U.S. Patent Nos. 7,266,175, 6,393,096, and 6,038,283.

[2] The fourth patent-in-suit is U.S. Patent No. 7,015,490. In this motion, Varian challenges all three asserted claims of the '175 patent but only three of the 16 asserted claims of the '096 and '283 patents because the sheer number of claims that BMI asserts makes it impossible to individually (or representatively) address each one within the page limits for this motion. Varian reserves the right and intends to move for summary judgment under Section 101 as to the remaining asserted claims of the '096 and '283 patents.

developed industry-leading software that helps physicians and dosimetrists plan cancer-treatment programs.

BMI has not developed such technology of its own. In 2007, BMI acquired the assets of Nomos Corporation, a legacy medical device manufacturer then in decline. D.I. 42 (First Am. Compl.) ¶ 22. The acquired Nomos assets included the four patents-in-suit. In October 2018, more than a decade later, BMI filed this lawsuit against Varian. D.I. 1. Two of the four patents-in-suit, the '096 and '283 patents, have expired. On July 21, 2020, this Court issued its Memorandum Order construing terms of the patents-in-suit. D.I. 134.

III. SUMMARY OF ARGUMENT AND STATEMENT OF FACTS

Varian submits that claims 13, 15, and 19 of the '175 patent, claims 44 and 46 of the '096 patent, and claim 42 of the '283 patent are invalid for claiming ineligible subject matter under Section 101. Varian presents facts relevant to the asserted claims in their respective subsections below.

IV. LEGAL STANDARD

Abstract ideas cannot be patented. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014). Whether a patent claims an ineligible abstract idea is a question of law that may be resolved on a motion for judgment on the pleadings. *Data Engine Techs. LLC v. Google LLC*, 906 F.3d 999, 1007 (Fed. Cir. 2018). A party may move for judgment on the pleadings "[a]fter the pleadings are closed—but early enough not to delay trial." Fed. R. Civ. P. 12(c).[3] In deciding this question of law, courts use the two-step test set forth in *Alice*.

[3] In the quoted excerpts throughout Varian's brief, all internal citations, quotation marks, and brackets have been omitted, and all emphases have been added, unless otherwise noted.

V. ARGUMENT

A. All asserted claims of the '175 patent are patent-ineligible.

The '175 patent concerns "controlling the correlation between the factors of treatment plan efficiency and dosimetric fitness" to optimize a radiation beam arrangement. '175, Abstract; *see also* D.I. 42 ¶ 188. Correspondingly, asserted claims 13, 15, and 19 are all directed to methods of controlling trade-offs between how long it takes to deliver radiation to a patient (treatment plan efficiency) and how closely the actual radiation delivered to the patient will match the ideal radiation dose distribution (dosimetric fitness). Claim 13 recites a method

> of providing control of a trade-off between treatment plan delivery efficiency and dosimetric fitness to optimize a radiation treatment plan within a continuum between delivery efficiency and dosimetric fitness, the method comprising the steps of:
>
> assigning a delivery cost term within an optimizer to each of a plurality of intensity maps representing a potential radiation beam arrangement, the assignment based on complexity of each respective intensity map; and
>
> evaluating an objective cost function for each of the plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the dosimetric cost term representing dosimetric fitness of the respective intensity map and the delivery cost term representing delivery efficiency.

Claim 15 depends from claim 13 and further recites a method

> wherein the delivery cost term represents at least one of the following: a segment count and an amount of total monitor units, to deliver radiation according to a beam arrangement represented by the respective intensity map.

Last, claim 19 recites a method

> of providing control of a trade-off between treatment plan delivery efficiency and dosimetric fitness to optimize a radiation treatment plan within a continuum between delivery efficiency and dosimetric fitness, the method comprising the steps of:
>
> evaluating an objective cost function within an optimizer for each of a plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the delivery cost term representing total monitor units to

> deliver radiation according to a beam arrangement represented by the respective intensity map; and
>
> rejecting each intensity map resulting in the delivery cost term exceeding a preselected threshold value.

All three '175 asserted claims, which recite this basic concept of balancing fitness and efficiency, fail both steps of the *Alice* test and are invalid under Section 101 for ineligible subject matter.

1. The '175 claims are directed to the abstract idea of optimizing a treatment plan based on tradeoffs between dosimetric fitness and treatment efficiency (*Alice* Step 1).

BMI concedes that the '175 patent is "directed to, *inter alia*, methods for controlling the correlation between the factors of treatment plan efficiency and dosimetric fitness to optimize the radiation therapy or radiotherapy plan." D.I. 42 ¶ 188 (citing '175, Abstract). And the '175 patent itself states that all the claimed optimization methods are "for enabling user control of the tradeoff between dosimetric fitness and delivery efficiency." '175 at 1:36–38. In short, the three '175 asserted claims are directed to the same abstract idea of optimizing a treatment plan based on tradeoffs between dosimetric fitness and treatment efficiency in an optimization algorithm.

Optimization based on data is a patent-ineligible abstract idea. In *OIP Technologies, Inc. v. Amazon.com, Inc.*, the Federal Circuit affirmed a trial court's decision granting a motion for judgment on the pleadings and found method claims reciting "a price-optimization method" to be directed to an abstract idea, despite optimization efficiencies that the patent purportedly introduced through generic computer functions. 788 F.3d 1359, 1361 (Fed. Cir. 2015). Likewise, in *In re Gopalan*, the Federal Circuit affirmed that claims directed to computer-implemented methods of optimizing measurements of spectral signals were in fact "directed to the abstract ideas of collecting and organizing data and the mathematical concept of optimization." 809 F. App'x 942, 945 (Fed. Cir. 2020).

Compounding the asserted claims' abstractness is their recitation of only aspirational results—and nothing about ***how*** the claimed optimization is purportedly achieved. Each claim recites "[a] method of providing control of a trade-off between treatment plan delivery efficiency and dosimetric fitness to optimize a radiation treatment plan." '175 at 6:5–9 (claims 13, 15), 6:48–52 (claim 19). But such result-oriented, functional claiming contravenes the requirement that a patent claim "sufficiently describe how to achieve [the] results in a non-abstract way," *Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1337 (Fed. Cir. 2017), rather than be "drawn to the idea itself," *Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1258 (Fed. Cir. 2016). For that reason, claim language in *Two-Way Media* that "require[d] the functional results of 'converting,' 'routing,' 'controlling,' 'monitoring,' and 'accumulating records,'" without explaining how to achieve those results, rendered the claims abstract under *Alice* step one. 874 F.3d at 1337; *see also Affinity Labs*, 838 F.3d at 1258 (invalidating claims that were "entirely functional in nature" for failing to recite "how to implement out-of-region broadcasting on a cellular telephone").

As the Federal Circuit explained in both *OIP* and *In re Gopalan*, the same principle applies to optimization patents. Claiming a method of optimization by way of increased efficiencies, as the '175 claims purport to do, does not depart from the realm of the abstract, especially where—as is true here—the claims do not recite ***how*** to achieve that optimization. Thus, in *OIP*, the court found the asserted claims to be "exceptionally broad" with "computer implementation limitations [that did] little to limit their scope." 788 F.3d at 1363. And in *In re Gopalan*, the court described claims that "only generically recite[d] 'a metric,' 'an optimization technique,' an 'optimization parameter,' 'a value of a number of independent measures,' and 'a value for a confidence measure'"—none of which were "defined," and none of which were

"concretely limit[ed] . . . such that the claims do not merely claim the result of obtaining a 'substantially optimal combination of true positives and false positives' in the data set." 809 F. App'x at 946. As a result, the claims "lack[ed] the specificity required to transform a claim from one claiming only a result to one claiming a way of achieving it" and "provide[d] result-oriented limitations like others we have held to be directed to abstract ideas." *Id.*

Here, the '175 claims—even viewed at the most granular level—do not "sufficiently describe ***how*** to achieve [the optimized results] in a non-abstract way." *Two-Way Media*, 874 F.3d at 1337. In fact, they do not describe how to achieve the claimed result at all. Instead, the claims simply recite the result of optimization, via purported user control of tradeoffs between dosimetric fitness and delivery efficiency, without saying how such tradeoffs occur or lead to that result. For example, claim 13 recites "assigning a delivery cost term within an optimizer to each of a plurality of intensity maps," and "evaluating an objective cost function for each of the plurality of intensity maps" where the cost function includes two cost terms. While the Court has construed intensity maps to mean "a representation of the variation across a defined area of radiation of a single beam," D.I. 134 (Memorandum Order regarding claim construction) at 11, that does not change the fact that claim 13 says nothing about how the claimed assignment or evaluation occurs, or how those limitations "provid[e] control of a tradeoff" between delivery efficiency and dosimetric fitness. Similarly, while the Court has construed "optimizer" to mean "program or device that iteratively attempts to find a preferred solution," *id.* at 10, the claims fail to describe or recite any particular ***way*** of achieving that preferred solution, or any other "specific technical solution beyond simply using generic computer concepts in a conventional way," *Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1352 (Fed. Cir. 2016).

Claim 15, which depends from claim 13, only defines what one of the cost terms represents and likewise does not identify any specific optimization method. And claim 19, which mirrors claim 13 but adds the step of "rejecting each intensity map resulting in the delivery cost term exceeding a preselected threshold value," does not specify what the "threshold value" is, how it is "preselected," how rejection of that value happens, or how the claimed optimization is achieved.

The abstract nature of the '175 asserted claims is further confirmed by their attempt to claim a mathematical formula. Where "a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory." *Parker v. Flook*, 437 U.S. 584, 595 (1978). Accordingly, the Federal Circuit in *RecogniCorp, LLC v. Nintendo Co., Ltd.* found that a claim directed to a method in which a user displayed images, assigned codes to those images "using a mathematical formula," and then reproduced images based on the assigned code, was directed to an abstract idea because "outside of the math, claim 1 of the [asserted] patent is not directed to otherwise eligible subject matter." 855 F.3d 1322, 1326–27 (Fed. Cir. 2017) ("Adding one abstract idea (math) to another abstract idea (encoding and decoding) does not render the claim non-abstract."). Even an "improved mathematical analysis" is abstract, particularly where "off-the-shelf computer technology is usable to carry out the analysis." *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1168 (Fed. Cir. 2018).

Here, the focus of the '175 asserted claims is an abstract "method of calculating," *Parker*, 437 U.S. at 595, as each claim is directed to the "evaluati[on of] an objective cost function" for treatment plan optimization. An "objective cost function" is a "***mathematical function*** that determines a cost value based upon objective factors." D.I. 134 at 8. Nothing in the claims

constitutes "otherwise eligible subject matter" that would take this mathematical function out of the realm of the abstract. *See RecogniCorp*, 855 F.3d at 1326–27. Instead, claim 13 provides only in general terms the composition of the objective cost function used for optimization ("the dosimetric cost term representing dosimetric fitness of the respective intensity map and the delivery cost term representing delivery efficiency"), while claim 15—which depends from claim 13—merely specifies a particular variable (segment count or total monitor units) to use as the cost function's "delivery cost term." Claim 19 echoes claim 13 except, like claim 15, it requires the delivery cost term in the cost function to represent total monitor units. All three claims recite nothing more than abstract mathematical functions with different variables. *See, e.g.*, *Parker*, 437 U.S. at 594–95 (claims reciting "process variables" were unpatentable).

The '175 specification further confirms the abstract nature of the asserted method claims by making clear that "off-the-shelf computer technology is usable to carry out the analysis" described therein. *See SAP Am.*, 898 F.3d at 1168; '175 at 1:19–20, 2:29–31 (claimed optimization can be performed on a "conventional linear accelerator provided with a multileaf, or multiple leaf, collimator" or on a "binary temporal modulator multileaf collimator").

Nor do the '175 asserted claims "fit into the class of [non-abstract] claims that focus on an improvement in computers and other technologies as tools." *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1371 (Fed. Cir. 2020) ("*CardioNet I*"). In *CardioNet I*, the Federal Circuit found the disputed claims to be patent-eligible, in part because the apparatus claims described a concrete arrangement of physical components (*e.g.*, "beat detector," "ventricular beat detector") that, taken together, did more than "merely invoke generic processes and machinery" and in fact constituted "technological improvements." *Id.* at 1368–69. But the three '175 method claims here are much closer to those in a later *CardioNet* case, where the Federal Circuit ***affirmed*** an

ineligibility finding under Section 101, in part because "the claims depend on methods that can be performed on any general-purpose computing device without reciting any nonconventional components or characteristics." *CardioNet, LLC v. InfoBionic, Inc.*, 816 F. App'x 471, 476 (Fed. Cir. 2020) ("*CardioNet II*"). Like the *CardioNet II* claims and unlike the *CardioNet I* claims, the asserted '175 claims do not describe an improved device. Instead, the sole component in these method claims is the optimizer which, as explained above, is a generic "program or device that iteratively attempts to find a preferred solution." D.I. 134 at 10.

The '175 claims are directed to optimizing a treatment plan but do not describe how to achieve that optimization. They are thus directed to an abstract idea under *Alice* Step 1.

2. The '175 claims do not contain an inventive concept (*Alice* Step 2).

The asserted '175 claims do not "involve more than performance of well-understood, routine, and conventional activities previously known to the industry" and thus lack an inventive concept. *Content Extraction & Transmission LLC v. Wells Fargo Bank, N.A.*, 776 F.3d 1343, 1347–48 (Fed. Cir. 2014). Indeed, the claim steps do not disclose "a specific technical solution beyond simply using generic computer concepts in a conventional way," *see Bascom*, 827 F.3d at 1352, and thus do not "transform the claimed abstract idea into a patent-eligible application," regardless of whether the steps are considered "individually" or "as an ordered combination," *OIP*, 788 F.3d at 1363.

Rather than providing any specific technical solution, the '175 claims recite abstract elements that do not give rise to an inventive concept. *See Trading Techs. Int'l, Inc. v. IBG LLC*, 921 F.3d 1378, 1385 (Fed. Cir. 2019) ("The abstract idea itself cannot supply the inventive concept, no matter how groundbreaking the advance."). Each step in the asserted method claims is a black-box function—*e.g.*, "assigning," "evaluating," "rejecting"—lacking any explanation of how those steps are carried out or how the claimed optimization result is achieved. And as

explained above, the only otherwise conceivably tangible component—the "optimizer"—is a generic "program or device" defined only by the abstract result to which it aspires (*i.e.*, it "iteratively attempts to find a preferred solution"). *See* D.I. 134 at 10. All that remains are the claims' recitations of "thresholds" and "algorithms," which are abstract mathematical concepts.

The rest of the intrinsic record confirms that these abstract ideas were themselves well known, and therefore could not provide an inventive concept even if they were non-abstract. Inventiveness is not a disputed fact issue because the applicant already admitted these points in the specification and during prosecution. For instance, the specification admits that the trade-off between dose distribution and treatment plan efficiency (also called "delivery efficiency") was well-known in the prior art. *See* '175 at 1:13–32 (describing "inefficient treatment plans" as a byproduct of optimizing for "the best calculated dose distribution"); D.I. 87-3 ('175 File History excerpt, Amendment & Response to Office Action Dated Oct. 25, 2006, filed Jan. 30, 2007) at 8–13 ("It was the Applicant's desire to develop tools/software . . . to allow the clinician to reduce dosimetric fitness (increase dosimetric cost) in an optimized plan in favor of enhanced delivery efficiency (e.g., lower segment count or lower total monitor units required) to thereby develop/form a radiation treatment plan.").

The '175 claims contain no more than abstract ideas, many of which were themselves well known. These admittedly conventional steps, described in purely functional or aspirational terms, do not transform the claims into patentable inventions.

B. Claims 44 and 46 of the '096 patent and claim 42 of the '283 patent are patent-ineligible.

According to BMI, the '096 and '283 patents "disclose products and methods for optimizing radiotherapy treatments." D.I. 85 (Joint Claim Constr. Br.) at 5. Both patents, which

share common inventors and substantially overlapping specifications,[4] are directed to "[a] method and apparatus for determining an optimized radiation beam arrangement." '096, Abstract. As BMI argued during claim construction, the patents claim "algorithmic operations" for determining an optimized beam arrangement. D.I. 85 at 33. These "algorithmic operations" are not claimed with any specificity in the challenged claims. They are also all mental processes, some of which are performed by people and others on a general-purpose computer.

1. '096 claims 44 and 46 and '283 claim 42 are unpatentable because they recite a functional result untethered to any way of achieving it.

A claim directed to achieving a result is unpatentable if it does not "sufficiently describe how to achieve [the] results in a non-abstract way." *Two-Way Media*, 874 F.3d at 1337; *see also* Section V.A.1, above. Claims 44 and 46 of the '096 patent and claim 42 of the '283 patent fail this test. To begin with, optimization techniques are unpatentably abstract, as discussed with respect to the '175 patent above. Moreover, BMI prevailed in arguing that the '283 and '096 claims are not limited to any "particular methodology for optimization." D.I. 85 at 3.

'096 claim 43 recites a method of:

> determining an optimized radiation beam arrangement for applying radiation to at least one tumor target volume while minimizing radiation to at least one structure volume in a patient, comprising the steps of:
>
> [1] distinguishing each of the at least one tumor target volume and each of the at least one structure volume by target or structure type;
>
> [2] determining desired partial volume data for each of the at least one target volume and structure volume associated with a desired dose prescription;
>
> [3] entering the desired partial volume data into a computer;
>
> [4] providing a user with a range of values to indicate the importance of objects to be irradiated;
>
> [5] providing the user with a range of conformality control factors; and

[4] Varian refers to "the specification" in the singular for language that appears in both patents.

> [6] using the computer to computationally calculate an optimized radiation beam arrangement.

Claim 44 depends from claim 43, and adds:

> The method of claim 43, further comprising the step of applying the optimized radiation beam arrangement to the patient with a conformal radiation therapy apparatus.

Claim 46 also depends from claim 43:

> The method of claim 43, wherein the optimized radiation beam arrangement is calculated using different cost function parameters depending on the target or structure type.

a. '096 claims 44 and 46 are directed to the abstract idea of optimizing a beam arrangement (*Alice* Step 1).

Claims 44 and 46 of the '096 patent recite a result (an optimized beam arrangement) without specifying how to achieve it. The '096 patent and its claims focus on this result, *see, e.g.*, '096, Abstract ("method and apparatus for determining an optimized beam arrangement"), without limitations on how it is calculated. Any general-purpose computer can do this optimization (as could a person, given enough time). Varian unsuccessfully advocated construing the "computer" that carries out the claimed optimization as structurally limited to a simulated annealing radiotherapy planning (SARP) algorithm. But the Court ruled that the '283 and '096 claims are not so limited, and thus the claimed "computer" is merely a general-purpose computer with no constraints on the algorithms it uses to achieve the claimed results.

"Stripped of excess verbiage," '096 independent claim 43 (from which claims 44 and 46 depend) requires describing treatment parameters, entering data, displaying data, and optimizing a beam arrangement. *Affinity Labs*, 838 F.3d at 1256. Namely, the claim recites the steps of: (1) distinguishing each of the targets and structures by type; (2) determining partial volume data for the targets and structures associated with a prescription; (3) entering the data into a computer; (4) providing the user with a range of "importance" factors; (5) providing the user with a range of "conformity control factors"; and (6) "using the computer to computationally calculate an

optimized beam arrangement." Each of these steps must be or could be performed by a human doing computations—*i.e.*, the original "computer." *See Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Canada (U.S.)*, 687 F.3d 1266, 1277–78 (Fed. Cir. 2012). And crucially, claim 43 contains no instructions for how the general-purpose computer is to perform the optimization calculation; the computer can optimize according to any algorithm or formula or consideration. '096 claims 44 and 46 do not add any limitations that describe how to achieve the claimed optimized beam result; they merely recite that unidentified variables should be used in an unspecified way (claim 46) or that the result be applied to a patient (claim 44).

The claims' focus is the optimization result, step 6. The specification repeatedly characterizes the invention as a method and apparatus for determining an optimized beam arrangement. *See, e.g.*, '096 Abstract; 5:54–55 ("improved optimized treatment planning system"). And the other claim steps are abstract ideas or routine functions that do not make the claims as a whole a concrete, specific solution. Step (1) refers to the human mental process of identifying or categorizing targets and structures. For example, the user can indicate the type of structure by checking "BU" or "BP" in a prescription panel. *See* '096, Fig. 5. The user makes that determination in their mind, and the claim language provides no guidance as to how the user should do it.

Step (2) also refers to a mental process performed by the prescribing physician, and step (3) refers to entering the result of that mental process into a computer. "The partial volume data generally describes what percent of the volume of a tumor or structure can receive how much dose." *Id.* at 6:66–7:1. The physician comes up with these data through their own mental analysis. *See, e.g.*, *id.* at 7:16–31 ("physician may determine" the percentage of the target volume that can receive a cumulative dose). Upon being entered into the computer, the partial

volume data goes into the ether, never again mentioned in the claims.

Then, steps (4) and (5) require providing a user with values or options (importance values and conformity control factors), but say nothing about how those values are developed; and, as with the partial volume data, the claims make no further mention of those values (*e.g.*, the claims say nothing about requiring the physician to ***select*** those values or requiring the computer to ***use*** those values). Claim 43 thus specifies no requirements about the importance values and conformity control factors other than that the computer display them. Presenting options to a user is an abstract idea, *see Apple Inc. v. Amaranth, Inc.*, 842 F.3d 1229, 1240 (Fed. Cir. 2016) (displaying menu of options is an abstract idea), and incidental to the result-oriented, optimization focus of the claims.

The limitations of dependent claims 44 and 46 likewise add nothing to the core abstract idea. Claim 44 requires applying claim 43's optimized result with an admittedly conventional apparatus, for its conventional purpose. *See* '096 at 5:64–66. Applying an optimized beam arrangement using a conventional radiotherapy apparatus does not make the abstract idea of claim 43 patentable. *See Parker*, 437 U.S. at 590.

Claim 46 requires that the optimized result of claim 43 be calculated "using different cost function parameters depending on the target or structure type." But claim 46 says nothing about ***how*** to use the cost function parameters. Base claim 43 does not require cost function parameters or describe how they are used to optimize. Dependent claim 46 also does not include any restrictions on how cost function parameters might be used to optimize, and thus is just as result-oriented as claim 43. Nor does claim 46 describe how the physician might determine the cost function parameters or how they might differ by structure or target type. The limitation added by claim 46 therefore amounts to an instruction to use different, but unidentified, variables

in an unidentified optimization process. This vague addition does not transform the claim from abstract to concrete.

Claims 44 and 46 are, therefore, directed to the aspirational result of an optimized beam arrangement—not concrete technology for accomplishing it. The result of optimization is an abstract idea, *see* Section V.A.1, above, and the claims are similar to those held by the Federal Circuit to be improper attempts to patent results. For example, in *In re Gopolan* (also discussed above), the claims at issue recited the steps of selecting measurements and metrics and "applying an optimization technique." 809 F. App'x at 943. Those claims failed to specify how the measurements and metrics were used, "but instead merely claim[ed] the desired result of optimizing the number of true positives and false positives." *Id.* at 944. Similarly, here the claims recite various physician-provided information or computer-displayed options, but fail to specify how that information is used, instead claiming the broad result of optimizing the beam arrangement.

At their core, the claims are like those held invalid in *Clairlogic, Inc. v. FormFree Holdings Corp.*, 681 F. App'x 950 (Fed. Cir. 2017). The *Clairlogic* claims required collecting data and then validating data "by applying an algorithm engine." *Id.* at 952. They were directed to an abstract idea because the "the algorithm engine mentioned in the claim is not claimed, identified, or explained." *Id.* at 954. Although that patent's specification provided some examples of how the algorithm engine could be programmed, the claims were not limited to those examples. *See* Ex. A (U.S. Patent No. 8,762,243) at 3:21–30. The Federal Circuit reasoned that "a method for collection, analysis, and generation of information reports, where the claims are not limited to how the collected information is analyzed or reformed, is the height of abstraction." *Id.* at 954. Here, the optimization step is akin to the *Clairlogic* "engine," in that

the optimization technique is not identified in the claims, which are not limited to the SARP algorithm disclosed in the specification. Thus, like in *Clairlogic*, claims 44 and 46 recite an optimization step but the claims are not limited to any "particular methodology for optimization." D.I. 85 at 3.

Nor do the claims implement the abstract idea as part of a specific, technological improvement. Rather, they are similar to those the court found unpatentable in *CardioNet II* because they implement the unspecified optimization process using a general-purpose computer. The claims do not purport to improve the functioning of a linac, radiation-therapy device, or even a computer. Tellingly, the specification does not tout a technological improvement akin to those in cases where courts have found patents directed to specific improvements to the functioning of a technology and not abstract ideas. For example, in *CardioNet I*, the specification said the invention actually improved the performance of cardiac monitoring devices, *e.g.*, by increasing their diagnostic accuracy. 955 F.3d at 1369–70. In contrast, here the specification touts no specific improvements or benefits to a device; instead, the purported improvement is just an implementation of the abstract idea itself. The specification identifies a problem with the way that physicians analyze the cost of potential treatments, not a problem with specific devices or technology. *See, e.g.*, '283 at 3:38–40 ("Existing cost functions utilized in the optimization of treatment plans do not account for such varying costs associated with the different types of structures."). And the purported solution of claims 44 and 46 does not address this problem, as it encompasses all optimized beam arrangements.

The claims are directed to an abstract idea because they focus on optimizing a beam arrangement through any procedure whatsoever, on a general-purpose computer.

b. '283 claim 42 is directed to the abstract idea of optimizing a beam arrangement associated with a CDVH (*Alice* Step 1).

Claim 42 of the '283 patent, dependent on claim 40, also claims an optimized result without specifying how to accomplish it. Claim 40 is a method of

> determining an optimized radiation beam arrangement for applying radiation to at least one tumor target volume while minimizing radiation of at least one structure volume in a patient, comprising the steps of:
>
> [1] determining desired partial volume data for each of the at least one target volume and structure volume associated with a desired dose prescription;
>
> [2] entering the desired partial volume data into a computer;
>
> [3] in response to the desired partial volume data, using the computer to computationally approximate desired CDVHs for each of the at least one target and structure associated with the desired dose prescription; and
>
> [4] using the computer to computationally calculate the optimized radiation beam arrangement associated with the CDVHs approximated by the computer.

And claim 42 adds:

> The method of claim 40, further comprising the step of applying the optimized radiation beam arrangement to the patient with a conformal radiation therapy apparatus.

Claim 40 thus recites the steps of (1) determining partial volume data; (2) entering the data into a computer; (3) in response, approximating CDVH curves for the target and structure; and (4) calculating an optimized arrangement "associated with the CDVHs." Claim 42 adds applying the optimized arrangement with a conventional apparatus, for its conventional purpose.

Compared to '096 claim 44 above, '283 claim 42 requires that the optimized arrangement be "associated with" a CDVH curve. But to the extent that this requirement cabins the optimized result at all, it does so only by way of a black box. The claim says nothing about ***how*** the computer should account for the CDVH when optimizing. Merely reciting an "association" with a CDVH does not specify that the optimized result actually ***use*** the CDVH—indeed, the claim language would purport to cover any link between the claimed optimization and the CDVH.

Thus, the "associated" language adds no meaningful limitation to the claimed optimization.

The other steps in '283 claim 42 refer to nothing more than abstract mental processes, routine data entry and display, and conventional application using a conventional apparatus. Steps (1) and (2) of '283 claim 42, determining partial volume data and entering them, are the same mental process as steps (2) and (3) of '096 claim 43 discussed above. Step (3) of '283 claim 42 is displaying the partial volume data graphically, which amounts to plotting the partial volume data points on a graph—per the '283 patent, "the partial volume data for a target may include data corresponding to values represented as data points on a target CDVH curve 100." '283 at 10:63–65. CDVHs are simply graphical representations of percent volume and dose (*i.e.*, partial volume data), as shown in Figures 3 and 4. *See id.* at 10:35–36, 63–65. Indeed, a physician can draw a CDVH curve: "the physician may be able to draw the target CDVH curve 100 graphically using a mouse or other pointing device and the system would then present the numeric values representing the target goals corresponding to the target CDVH curve 100." *Id.* at 11:31–35. BMI admits that a CDVH is a way to visualize "the amount of radiation that is to be delivered to the tumor and to surrounding tissues." D.I. 85 at 12. Converting information from one format (partial volume data) to another (corresponding CDVH) is a routine, abstract step that does not change the fundamental character of the claim. *See, e.g., SAP Am., LLC*, 898 F.3d at 1167 (displaying results is abstract). Nor do the claims describe a specific technological solution, for the same reasons as claims 44 and 46 of the '096 patent. As the additional steps are themselves mental processes or routine steps, they do not change the focus of the claim from the abstract idea: optimization associated with a CDVH.

2. None of the claims contains an inventive concept (*Alice* Step 2).

Like the '175 claims, '096 claims 44 and 46 and '283 claim 42 simply apply the recited abstract idea using a computer and in a conventional context and do not purport to improve

computer or linear accelerator technology; they therefore do not contain an inventive concept. The Court can decide this question without resolving factual disputes because the patent specification concedes that the additional limitations are conventional. *See, e.g.*, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 79 (2012) (looking to patent specification for evidence that step was well known in the art); *Berkheimer v. HP, Inc.*, 890 F.3d 1369, 1371 (Fed. Cir. 2018) ("In a situation where the specification admits the additional claim elements are well-understood, routine, and conventional, it will be difficult, if not impossible, for a patentee to show a genuine dispute.") (Moore, J., concurring in denial of reh'g en banc).

- The only tangible component required is a general-purpose computer. But using the claimed general-purpose computer to calculate an optimized beam arrangement does not add an inventive concept. *In re Gopalan*, 809 F. App'x at 946 (performing an "optimization technique on a generic processor does not transform it into a patentable apparatus"). Likewise, using a computer to display options and receive data entry is routine and not inventive.
- The steps of determining partial volume data and plotting data as CDVH curves were "conventional" and "familiar" concepts in radiation therapy. '283 at 3:49, 9:53–55, 10:26–28, 10:35–43, 11:24–26, 12:2–4, 12:48–52. They cannot provide an inventive concept.
- Applying the optimized beam arrangement using a "conformal radiation therapy apparatus" does not add an inventive concept, as the specification also admits that this step involves using conventional equipment in a conventional manner. '283 at 8:33–35 (referring to Fig. 1), 9:59–64; *see also* D.I. 42 ¶ 23 ("Conformal radiation therapy typically uses a linear accelerator ('LINAC')[.]").

VI. CONCLUSION

In the challenged claims, BMI is attempting to enforce a monopoly on the concept of optimizing beam arrangements in radiation therapy. While the patent specifications may provide some insights or examples into how one might perform that optimization, the claims include none of that detail. Instead, the challenged claims are directed to the generic, aspirational result of an optimized beam arrangement. This result can be calculated by any general-purpose computer, or even done in the human mind. Varian, therefore, respectfully requests that the Court grant its motion and find claims 13, 15, 19 of the '175 patent, claims 44 and 46 of the '096 patent, and claim 42 of the '283 patent directed to ineligible subject matter and invalid under 35 U.S.C. § 101.

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